UK BioIndustry Association

Human Gene Editing

BioIndustry Association policy view – January 2016

1. The BioIndustry Association (BIA) is the UK trade association for innovative bioscience enterprises, with member organisations engaged in life sciences research and development (R&D). As such, the BIA represents organisations whose work may be impacted upon by recent advances in genome editing and specifically human gene editing. This paper reflects the outcome of discussions on the topic of human gene editing by the BIA Board in January 2016.

2. The BIA notes that Regulations to allow mitochondrial donation have been approved by UK Parliament and that these have been in force since October 2015 in the UK as part of the work of the Human Fertilisation and Embryology Authority (HFEA).

3. Furthermore, on 1 February 2016 the HFEA approved an application from a research group at the UK based Francis Crick Institute to use gene editing techniques on human embryos[1].

4. The BIA welcomes the Hinxton Group's 2015 position on Human Gene Editing[2] and the initial joint statement of the Academy of Medical Sciences, the Association of Medical Research Charities, the Biotechnology and Biological Sciences Research Council, the Medical Research Council and the Wellcome Trust on Genome Editing in Human Cells of September 2015[3].

5. BIA also welcomes the International Summit Statement on Human Gene Editing of December 2015, and notes in particular its conclusions on germline editing for clinical use. **BIA agrees with the following principles** set out in the International Summit Statement:

    a. **"It would be irresponsible to proceed with any clinical use of germline editing unless and until** … **there is broad societal consensus about the appropriateness of the proposed application**. **Moreover, any clinical use should proceed only under appropriate regulatory oversight**. … **[As] scientific knowledge advances and societal views evolve, the clinical use of germline editing should be revisited on a regular basis**."

6. As a key UK industry representative body, we look forward to engaging with this developing policy area. The BIA would like to see a consensus position reached between UK scientists, society and policy-makers that will enable businesses that may emerge from this frontier science to establish themselves in a supportive and properly regulated environment in the UK.

[1] The Francis Crick Institute (01 February 2016) Press release https://www.crick.ac.uk/news/science-news/2016/02/01/hfea-decision/
[2] The Hinxton Group (2015) 2015 Statement http://www.hinxtongroup.org/hinxton2015_statement.pdf
[3] Wellcome Trust et al (2015) Joint statement on genome editing in human cells http://www.wellcome.ac.uk/About-us/Policy/Spotlight-issues/Genome-editing/WTP059704.htm

About the BIA

Established in 1989, the BioIndustry Association (BIA) is the UK trade association for innovative bioscience enterprises. BIA members include emerging and more established bioscience companies, pharmaceutical companies, academic research and philanthropic organisations, and service providers to the UK bioscience sector. The BIA also runs specialist industry groups in two of the 'Eight Great Technology' areas identified by the Chancellor George Osborne, namely synthetic biology and regenerative medicine.

Our members are responsible for over ninety per cent of biotechnology-derived medicines currently in clinical development in the UK and are at the forefront of innovative scientific developments targeting areas of unmet medical need. This innovation leads to better outcomes for patients, to the development of the knowledge-based economy and to economic growth. Many of our members are small, pre-revenue companies operating at the translation interface between academia and commercialisation.

This policy view paper reflects the outcome of discussions by the BIA's Board. For additional information or clarification on any of the points raised please contact Zoë Freeman, Policy and Public Affairs Manager, on zfreeman@bioindustry.org or on 020 7630 2187.